BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

REMARKS

The action by the Examiner of this application, together with the cited references, have been given careful consideration. The objection to claim 13 has been addressed by the present amendment. It is respectfully requested that the Examiner reconsider the 35 U.S.C. Section 103 rejection based upon the combined teachings of U.S. Patent No. 2,990,838 to Cross and U.S. Patent No. 5,537,998 to Bauman, in view of the following comments. In particular, the following should be noted:

(a) The present invention provides a flow rate control valve (i.e.: flow volume/time) to control the rate of one way inspiration gas delivery, whereas Cross teaches a flow direction control valve to isolate fresh inspiration gas flow (moving right to left in Fig. 7) from contaminated expiration gas flow (moving in the opposite direction left to right in Fig 1);

(b) The present invention has a valve plug (11) that is normally biased away from the valve seat (12) as claimed. The Examiner has misstated in paragraph 6 that Cross also has a valve seat (18) and a valve plug where the valve plug is normally biased away from the valve seat. The Examiner's statement is clearly contrary to the Cross specification at Col 2 line 58-65 where it is stated that "The valve member 16 is urged into seating relationship with the valve seat member18 by the action of a resilient compression spring member 20..."

Amendments have been made to claim 1 to clarify the distinguishing features of the invention and to distinguish over the cited references. It is respectfully requested the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

The Examiner has raised *new* prior art US 2,990,838 to Cross and rejected the claims 1-3 and 8-14 under 35 U.S.C. 103(a) as being obvious by US 2,990,838 to Cross in view of U.S. Patent No. 5,537,998 to Bauman. It is respectfully submitted that neither Cross nor Bauman, taken individually or in combination, teach or suggest the applicant's invention as presently set forth in claim 1.

United States Patent No. 2,990,838 to Cross teaches a directional control valve. At Column 1, commencing at line 35, it is stated that the primary object of the Cross invention is

to provide improved valving means for permitting fluid from the operator to pass to the patient (inspiration) while upon return of exhaust fluids from the patient (expiration) causing these to vent to the atmosphere and be prevented from returning to the mouth of the operator.

This function of the valve can clearly be seen in comparing the inspiration position shown in Figure 7 with the expiration position shown in Figure 1. Referring to Column 2, commencing at line 56, the movable valve member 16 cooperates with affixed valve seat structure 18. The valve member 16 is urged into seating relationship with the valve seat member 18 by the action of the resilient compression spring member 20 acting at its right-hand (as viewed in Figure 1) upon the valve member 16 and acting at his left-hand end upon a spring-retaining means 22 fixed within the body member.

It is stated commencing at Column 2, line 69 that in Figure 1 the valve member 16 is shown in its seated position at its extreme movement to the right as viewed in Figure 1. The Examiner will appreciate that the spring 20 is compressed between the movable valve member 16 and the spring retaining means 22 and exerts a biased force to urge the valve member 16 into engagement with the valve seat member 18 (i.e.: the inspiration path is normally closed, while the expiration path is normally open). In the position shown in Figure 1 therefore the patient expires gas which escapes through lateral port openings 26 in the wall of the body member 10A.

As stated at Column 4 commencing at line 42, in this position of the valve member 16, the port 26 becomes unobstructed and fluids issuing from the patient now pass freely through the port 26 to atmosphere. Insofar, as there may be such pressure of fluid issuing from the patient as to cause an accumulation of pressure within the body member 10a due to the resistance of passage through the port 26, this will only more firmly seat the valve member 16 into the valve seat structure 18 and the passage of these possibly contaminated fluids to the operator's mouth will be completely precluded.

Therefore, as described in the specification and shown in the drawings in Figure 1, Cross describes a valve which redirects the expiration gases from the patient to the atmosphere through ports 26 while the spring 20 retains the valve member 16 in sealing engagement with the valve seat 18 completely separating the expiration flow gas from the inspiration flow gas.

Turning to the position adopted in Figure 7 and Column 4 commencing at line 6, the Cross inspiration position will be described. Figure 7 shows the position of the valve member 16 during the first phase (inspiration) of the cycle while the operator is blowing air into the mouth piece 12. When this fluid pressure is presented to the seated valve, pressure is exerted upon the face 16e and there is a "minimum of leakage" of this inspiration gas/fluid until the portion 16d of the valve member has substantially removed itself from the aperture 30 of the valve seat structure. Unseating movement of the valve member 16 will not terminate until a position is achieved more less as shown in Figure 7 where upon the fluid now escaping around the outside of the aperture 30 and around the portion 16d of the valve member passes through the aperture 16g of the valve member and then past the spider 22. While the valve member 16 is in the unseated position as shown in Figure 7, the first portion 16a of the valve member blocks or obstructs a port opening 26 in the wall of the body member 10a. This is necessary in order to preclude the possibility of the operator's air passing to atmosphere rather than to the patient.

Further, at Column 4, commencing at line 38 it is stated that in the next stage of the resuscitation cycle when the operator has ceased blowing into the mouthpiece 12, the resiliency of the spring 20 will cause the valve member 16 to move so that seating occurs between the edge 18b and the face 16e. In this position of the valve member the port 26 becomes unobstructed and the patient's expiration gas passes through port 26 to the atmosphere.

As presented in the specification of Cross therefore, the teaching presented relates to a directional control valve which separates air expired from the patient as shown in Figure 1 from air passing to the patient during installation as best shown in Figure 7.

It is respectfully submitted that the Examiner has misstated the nature of Cross alleging that the valve plug 16 is normally biased away from the valve seat 18. However, this is clearly contrary to the Cross specification as explained above in detail. At Column 2, line 58 to 65 it is stated that the "valve member 16 is urged into seating relationship with the valve seat member 18 by action of the resilient compression spring member 20."

Further, Cross teaches that the resistance offered by the spring 20 must be "quite small" which teaches away from the present invention where the resistance of the spring is used to accurately control the rate of gas flow. In other words, Cross provides a rapid open-close

switch with a minimal resistance spring 20 whereas the present invention provides a spring loaded valve plug 11 that gradually and predictably resists movement toward the valve seat 12 to ensure accurate control of the flow rate by restricting the flow rate control orifice defined between the plug and seat.

The Examiner's attention is directed to Column 4 commencing at line 64 and proceeding to column 5 line 11. In Cross it is stated, that it is to be appreciated that pressure applied to fluids moving into a patient's lungs cannot exceed modest amounts. The present invention also recognizes that it is undesirable to exceed a modest pressure applied to the patient's lungs. The present invention provides a means to control the rate of inspiration gas delivery. In contrast, Cross raises this issue merely to point out that the spring 20 must have a relatively small resistance and the motion of the valve member 16 may be impeded by surface tension due to moisture accumulation.

Therefore, Cross raises the issue of spring 20 resistance and modest pressure apply to patient's lungs to explain that the valve member 16 must not become stuck and thereby require the operator to exert high pressure to move the valve member 16 from its seated position.

Cross provides ridges 16c and further reduces resistance or sticking due to the presence of moisture by providing the valve seating parts with a sharp edge 18b.

Therefore, Cross does not teach nor suggest use of the valve member 16 to control the rate of flow. In contrast, Cross teaches that the valve member 16 should experience minimal resistance to motion from the spring 20 and from surface tension caused by moisture accumulation to quickly switch between the expiration position shown in Figure 1 and the inspiration position shown in Figure 7.

The present invention provides a valve plug that together with a valve seat defines a flow rate control orifice between the valve seat and the valve plug. Cross does not provide such a flow rate control orifice between the valve seat and valve plug. Cross does not teach a flow rate control orifice but rather has two openings namely port 26 and central aperture 30 which are alternatively completely open or completely closed. The small resistance of the spring 20 and ridges 16c of Cross are specifically provided to ensure that the valve plug moves rapidly between the open and closed positions.

Cross does not contemplate the position of the valve plug between completely open and completely closed, except to concede that there will be a "minimal leakage" of inspiratory gas to atmosphere when the valve plug begins to be initially unseated.

The Cross reference merely teaches a flow direction control valve that moves between two extreme positions for inspiration and expiration to prevent mixing of contaminated expired gas with fresh inspiration gas.

The Bauman reference merely teaches use of pressure relief valves which exhausts excess pressure to the atmosphere.

In contrast, the present invention discloses a flow rate control valve with a valve seat and a valve plug normally biased away from the valve seat, by a spring. The plug is urged towards the valve seat to restrict the flow control orifice, by the force exerted by gas flowing and impinging against the gas flow impingement surface.

Resistance to flow caused by the flow rate control valve creates a back pressure and the back pressure translates into a firm bag which serves as a tactile feedback message to warn the user that excessive physical force is being applied to the bag. Over pressure caused by excessive squeezing of a conventional bag with no flow rate control valve can lead to gastric distension and aspiration of the stomach contents which can cause the patient to choke on their own vomit and result in medical complications even leading to death.

The cited references alone or in combination do not teach or suggest the solution taught by the invention involving control of the flow rate.

The remaining pending claims depend from claim 1, thus it is respectfully submitted that these claims are patentable over the prior art for at least the reasons set forth above in connection with claim 1.

The prior art made of record and not relied upon has also been reviewed. It is respectfully submitted that none of these additional references teach or suggest the applicants' invention as defined by the present claims.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters

which need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. SW7255US.

Respectfully submitted,

Date: March 25, 2004

Michael A. Jaffe
Registration No. 36,326

Kusner & Jaffe
Highland Place – Suite 310
6151 Wilson Mills Road
Highland Heights, Ohio 44143
(440) 684-1090 (phone)
(440) 684-1095 (fax)

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date: March 25, 2004

Crystal Belknap